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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,560	09/11/2006	Kurt Schoengendorfer	33412US-PCT	3703
72554	7590	12/18/2008		
SANDOZ INC 506 CARNEGIE CENTER PRINCETON, NJ 08540			EXAMINER KOSSON, ROSANNE	
			ART UNIT 1652	PAPER NUMBER
			MAIL DATE 12/18/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/575,560

**Applicant(s)**

SCHOERGENDORFER ET AL.

**Examiner**

Rosanne Kosson

**Art Unit**

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-24 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/ISD)
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☒ Other: alignments
- Paper No(s)/Mail Date: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

The following restriction applies to an amended claim set containing 24 claims filed on April 11, 2006. The file for this application, however, contains a claim set with a later filing date (April 18, 2006) that appears to be the original claims. Because the claims were amended, the amended claim set was reviewed for restriction. If, however, Applicant's intent was that the original claim set should replace the amended claim set, Applicant should communicate that intention in writing. Additionally, the claim set filed on April 18, 2006 should then be corrected with appropriate status identifiers for each claim ("currently amended").

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-3, 5, 7-21 and 24, drawn to a polynucleotide encoding the polypeptide of SEQ ID NO:1, a polynucleotide comprising SEQ ID NO:3, an expression vector and a host cell comprising SEQ ID NO:3, and a method of culturing the transformed host cell containing SEQ ID NO:3 to produce a penicillin.

Group 2, claim(s) 4, 7-21 and 24, drawn to a polynucleotide comprising SEQ ID NO:2, an expression vector and a host cell comprising SEQ ID NO:2, and a method of culturing the transformed host cell containing SEQ ID NO:2 to produce a penicillin.

Group 3, claim(s) 6-21 and 24, drawn to a polynucleotide comprising SEQ ID NO:4, an expression vector and a host cell comprising SEQ ID NO:4, and a method of culturing the transformed host cell containing SEQ ID NO:4 to produce a penicillin.

Group 4, claim(s) 22-23, drawn to a polypeptide comprising the polypeptide of SEQ ID NO:1.

The inventions listed as Groups 1-4 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons.

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The requirement of unity of invention is not fulfilled because there is no technical relationship among these inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" means those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. Therefore, a technical relationship is lacking among the claimed inventions involving one or more special technical features. The technical feature that links the 5 groups of inventions is a 4'-phosphopantethein transferase.

The inventions of Groups 1-4 do not share the common special technical feature of a 4'-phosphopantethein transferase, because Sanchez et al. ("Cloning and characterization of a phosphopantetheinyl transferase from *Streptomyces verticillus* ATCC15003, the producer of the hybrid peptide-polyketide antitumor drug bleomycin," Chem Biol 8:725-738, 2001) disclose the genus of 4'-phosphopantethein transferases (see Abstract and pp. 725-727). Moreover, SEQ ID NOS:2-4 encode three different proteins, with SEQ ID NO:3 encoding SEQ ID NO:1 (see protein translations made using the NCBI ORF finder at <http://www.ncbi.nlm.nih.gov/gorf/gorf.html>).

Thus, the technical feature of a 4'-phosphopantethein transferase does not define the invention over the prior art. Because the common technical feature is not novel (special) with respect to the cited reference, it is clear that the claims of Groups 1-4 lack a single common technical feature that defines them over the prior art.

The following text regarding linking claims has been added, because claims 4, 5 and 6 have been written to depend from claims 1 and 3. As discussed above, however, only SEQ ID NO:3 appears to encode the protein of SEQ ID NO:1. Nevertheless, if Applicant can demonstrate unequivocally that SEQ ID NOS:2 and 4 do encode the protein of SEQ ID NO:1, the following linking claims analysis will apply.

Claims 1 and 3 link(s) the inventions of Groups 1, 2 and 3. The restriction requirement among the linked inventions is **subject to** the nonallowance of the linking claim(s), claims 1 and 3. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall be** withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104. **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection

are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

If Applicant elects Group 2 or Group 3, if claims to the elected polynucleotide sequence are found to be allowable, and, if Applicant has clearly demonstrated that all of the claimed polynucleotides do encode the protein of SEQ ID NO:1, claim 1, the linking claim, will then be examined. If claim 1 is found to be allowable, next, the withdrawn polynucleotide claims will be examined.

Regarding the different claimed sequences, Applicants must choose **ONE** polypeptide or one polynucleotide from among those claimed as indicated in the different groups above. Each sequence is a distinct invention requiring separate searches. **THESE ARE NOT SPECIES.** Each sequence is a chemically, structurally and functionally distinct molecule. Therefore, the each of the polynucleotides is patentably distinct.

Moreover, each sequence requires a separate set of searches. Applicants should note that searching each sequence imposes a serious search burden. Currently, there are approximately eight different databases that accompany the results of a search for one discrete amino acid or nucleic acid sequence, and each result set from a particular database must be carefully considered. Each set of prior art has its own considerations with respect to anticipation and obviousness. Hence, the search for even two different polypeptides or polynucleotides in

the databases, in addition to searching the organic molecule databases, would require extensive searching and review. Therefore, these inventions are patentably distinct.

**Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).**

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is (571)272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Rosanne Kosson

Examiner, Art Unit 1652

rk/2008-12-08

/Delia M. Ramirez/

Primary Examiner, Art Unit 1652